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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,663	01/29/2004	Yossi Gross	SC&C-100US	5982
23122	7590	10/18/2007		
RATNERPRESTIA P O BOX 980 VALLEY FORGE, PA 19482-0980			EXAMINER MAEWALL, SNIGDHA	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,663

Applicant(s)

GROSS ET AL.

Examiner

Snigdha Maewall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-130 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-130 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/08/2004, 11/26/2004, 05/13/2005, , 08/28/2006, 02/22/2007, 04/23/2007.

DETAILED ACTION

Summary

1. Receipt of IDS filed on 08/11/2004, 10/08/2004, 11/26/2004, 05/13/2005, 08/28/2006, 09/16/2005, 02/22/2007 and 04/23/2007 is acknowledged.

Restriction/Election

2. Applicant's election without traverse of Group I claims 1-130 in the reply filed on 07/23/2007 is acknowledged.

Claims 131-173 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/23/2007.

Claims 1, 27, 31, 34, 48, 51, 52, 63, 71, 78, 87, 97, 100-101, 129 and 130 have been amended. Claims 131-173 have been withdrawn from the prosecution.

Accordingly, claims included in the prosecution, which read on elected invention, are Claims 1-130.

DOUBLE PATENTING

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-130 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-209 of copending Application No. 10/901742. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the applications comprise overlapping subject matter. The claims of the copending application are drawn to an apparatus for drug administration comprising an ingestible capsules comprising, a drug, environmentally sensitive mechanism and sensors etc. as claimed in an instant application. The only difference between the two applications is between various current and pulse parameters, optimization of which would be within the purview of a skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-130 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-241 of copending Application No. 11/579246. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the applications comprise overlapping subject matter. The claims of the copending application are drawn to an apparatus for drug administration comprising an ingestible capsules comprising, a drug, environmentally sensitive mechanism and sensors etc. as claimed in an instant application. The only difference between the two applications is between various current, frequency and pulse parameters, optimization of which would be within the purview of a skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-130 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-209 of copending Application No. 10/838072. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the applications comprise overlapping subject matter. The claims of the copending application are drawn to an apparatus for drug administration comprising an ingestible capsules comprising, a drug, environmentally sensitive mechanism and sensors etc. as claimed in an instant application. The only difference between the two applications is between various

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current, frequency and pulse parameters, optimization of which would be within the purview of a skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-130 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitation "environmentally sensitive mechanism" and driving mechanism". The claim does not recite any structural limitations of the components of the apparatus. In the absence of such the structural and functional relationship cannot be deduced. The generic recitation does not portray the structure /function relationship of the apparatus claimed.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "environmentally sensitive mechanism and 'driving mechanism'". The claim is indefinite because the metes and bounds of the claim are not defined. It is not clear what compounds or items are included which promote the environmentally sensitive mechanism or driving mechanism. The two limitations are processes and as recited are governed by some item or compound or component within the apparatus. Since the items/compounds/components are missing, the claim is rendered indefinite. Appropriate correction is requested.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. Claims 1-57, 59-87 and 89-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2374149 A Patent to (Thomas et al.) in view of the combination of references of (Kobonez et al. US Patent No. 6,453,199 B1, Gross et al. US Patent No. 5,925,030 and Yona et al. WO02/098501).

Thomas et al. teaches a swallowable intrabody drug-dispensing capsule comprising a capsule with a sensing module (chemical or electrical), a bio active substance dispenser. The sensing module detects one or more biological conditions within a body. The picture on the front page depicts an embodiment showing drug release into the human digestive system. (abstract). Thomas et al. also disclose a method of drug delivery using the medical device. Thomas et al. further disclose that ingestible medical capsules are known which are capable of sensing a condition such as pH, temperature within the digestive tract and then transmitting that sensed data to receiver to help identify a body location for dispensing a drug (page 3, lines 1-5). The transmitter and receiver are disclosed as wireless communication aids which helps in initiating drug delivery (see page 8, lines 10-30). A suitable power supply includes lithium battery which is non toxic to the body (page 10, lines 10-20). Sensing module can be selected to sense absolute values of pH and also could sense presence of unexpected digestive tract constituent such as blood or cancer cells (see page 17, lines 17-25).

Thomas does not teach driving mechanism comprising electrodes, control units etc.

Kobozev teaches an invention which relates to medical technology and comprises electrical gasro-intestinal tract and mucous membrane stimulators. The gastrointestinal stimulator comprises electrodes, a device for receiving signals from internal organs and

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/or external transmitter. The stimulator can comprise additional electrodes. The dimensions of the stimulator can be such that it can be used orally, rectally or vaginally (abstract). The control unit, pulse generator, receiver transmitter are depicted in figure 4. The control unit can also send pulse series to the electrodes and change pulse parameters(current, voltage, duration, frequency etc.). Kobozev further suggests that the electrode be made from non-toxic biologically neutral materials (see the detailed description on column 7, lines 30-55).

Kobozev does not teach self expansible portion, however, Gross et al. teaches self expansible portion in a capsule.

Gross et al. teaches oral drug delivery device having a housing with walls of water permeable material and having at least two chambers separated by a displaceable membrane. The first chamber receives drug and has orifice through which the drug is dispensed under pressure. The second chamber includes electrode forming a part of electrical circuit, which is closed by the ingress of an aqueous ionic solution into the second chamber. When the current flows through the circuit, gas is generated and acts on the displaceable membrane to compress the first chamber and expel the active ingredient through the orifice (abstract). Gross et al. further discloses that the electric circuit can include sensors such as pH sensor, to effect delivery of the drug to the predetermined region of the gastrointestinal tract, a temperature sensor, sound sensor. Such biosensors can provide feedback to the electric circuit (see column 3, lines 20-30). Various active ingredients can be solid, liquid or semi solid (column 5, lines 62-65).

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Yona et al. also discloses a method of treating tumor tissue of an individual. The apparatus requires electrode system. The electrode system is in communication with power source and provides AC input and DC output (see page 23, lines 25-30). Various frequencies and electric field pulses are disclosed on page 24, lines 5-25). The apparatus includes an injector mechanism which serves for injecting a cytotoxic agent. (see page 25, lines 5-20 and claims).

Based on the teachings of the above cited references, it would have been obvious to the one of ordinary skill in the art at the time the invention was made to include driving mechanism comprising control unit pulse generator and multiple electrodes as forwarded by Kobozev et al. and Yona et al. in the teachings of Thomas et al. and Gross et al. which teaches environmentally sensitive mechanism comprising pH sensor and self expandable system taught by Gross et al. with an expectation of obtaining a driving mechanism which is adapted to drive current through the electrode. A skilled artisan would have been motivated to formulate an ingestible capsule comprising drug, an environmentally sensitive mechanism adapted to undergo the change of state when the capsule is in various stages of gastrointestinal tract with a reasonable expectation of success.

13. Claims 58 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2374149 A Patent to (Thomas et al.) in view of the combination of references of (Kobonez et al. US Patent No. 6,453,199 B1, Gross et al. US Patent No. 5,925,030

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and Yona et al. WO02/098501) and further in view of Leonard et al. (Pharmaceutical research vol. 17, no. 4, 2000).

The references taught above do not disclose iontophoretic current between the first and the second electrode. However, Leonard et al. has shown the iontophoresis- enhanced absorptive flux of polar molecules across intestinal tissue in vivo. Leonard et al. further disclose that the eletrophoretic manipulations can modify intestinal absorption of drugs that have otherwise low bioavailability after oral administration (see last paragraph on page 478).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to introduce iontophoretic current between the electrodes in ordr to obtain better absorption of the drugs with a reasonable expectation of success.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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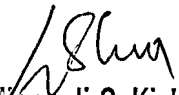
published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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